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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/599,203

09/22/2006

Yoshinobu Yamazaki

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SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER

PAGONAKIS, ANNA

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

10/05/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/599,203	Applicant(s) YAMAZAKI ET AL.	
	Examiner ANNA PAGONAKIS	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9-15-09.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 1-10, 15 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-14, 17 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment filed 9/15/2009 has been received and entered into the present application. Applicant's arguments filed 9/15/2009 have been fully considered. Rejections not reiterated from previous Office Actions hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

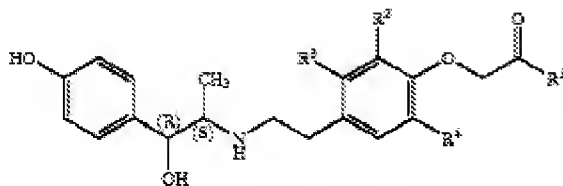
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11-14, 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka et al (WO 00/02846, cited as a functional language equivalent is U.S. 6,538,152) in view of Broten et al (U.S. 6,410,554) in light of the Mesh Supplementary Data (2009).

Tanaka et al teach the administration of the compound:

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where R₂ and R₃ are each lower alkyl groups and pharmaceutically acceptable salts thereof, for the treatment of urinary incontinence (abstract).

Broten et al teach administration of KMD-3213 for the treatment of lower urinary tract symptoms which including increasing urine flow rate, decreasing residual urine volume and improving overall obstructive and irritative symptoms in patients with benign prostatic hyperplasia or symptomatic prostatism (column 5). KMD-3213 can be administered at a dosage from about 0.01 mg to about 500 mg per subject (column 13).

Mesh Supplementary data teaches that KMD-3213 is an alternative name for silodosin.

Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the references so as to administer silodosin (alpha-adrenoreceptor antagonist) in combination with ethyl(-)-2-[4-[2-[[[(1S,2R)-2-hydroxy-2-(4-hydroxyphenyl)-1-ethylethyl]amino]ethyl]-2,5-dimethylphenoxy]acetate in view of teachings of Tanaka et al and Broten et al. One would have been motivated to do so because each of the therapeutics have been individually taught in the prior art to be useful for the treatment of urinary incontinence. Therefore, the idea of combining administration of the two agents flows logically from their having been individually taught in the prior art. Applying the same logic to the instant claims, one of ordinary skill in the art would have been imbued with a reasonable expectation of success that administration of both agents would be useful for the treatment of urinary incontinence.

With respect to claim 17, the determination of a dosage having the optimum therapeutic index while minimizing adverse and/or unwanted side effects is well within the level of the skilled artisan. The dosage is clearly a result effective parameter that a person of ordinary skill in the art would routinely

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optimize. Optimization of parameters is a routine practice that would have been obvious for a person of ordinary skill to determine the optimal dosage needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of dosages would have been obvious at the time of Applicant's invention.

Response to Applicant's Remarks

Applicant alleges that Broten et al. describes that an alpha-1A adrenergic receptor antagonist is useful in treating BPH and inhibiting contraction of the lower urinary tract tissue which one of ordinary skill in the art might expect an effect of relaxing the urinary tract and improving urine outlet however would not expect any effect regarding treating urinary frequency or incontinence. This is not found persuasive. Applicant fails to advance any specific reasons or evidence aside from Counsel's own allegation, in support of this position. This assertion by Counsel is an unsupported allegation and fails to take the place of evidence in the record. Statements of this nature are clearly unpersuasive in accordance with the guidance provided at MPEP 2145. In contrast to Applicants conclusions, one skilled in the art could also reasonably conclude that improving urinary outlet would reduce the symptom of urinary frequency in BPH.

Applicant alleges that the instant disclosure supports unexpected results in Example 2 and Figure 2 in the combination of silodosin and compound 2. This is not found persuasive. In order for superadditive or superior results to be concluded, each agent must be administered at the same dosage and then the combination of the two agents compared to the change of micturition interval demonstrated by each individual agent. In the instant case, the same dosage of silodosin and compound 2 have not been administered as such it cannot be concluded that the combination is unexpectedly superior. Further, it seems that the combination of the two agents do not provide superadditive or superior results.

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Conclusion

No claim is found to be allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNA PAGONAKIS whose telephone number is (571)270-3505. The examiner can normally be reached on Monday thru Thursday, 9am to 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AP

/Patricia A. Duffy/
Primary Examiner, Art Unit 1645